Toothpastes (Dentifrices)

What’s so great about them?

History of Toothpastes

- Dentifrices date back over 2000 years
- Colonial America
  - mixed own powders and pastes
    - became popular with re-invention of toothbrush by William Addis about 1770.
- Dentifrices usually a “family pot”
- Invention of the toothpaste tube
  - 1892 by Dr. Washington Wentworth Sheffield

History of Toothpastes (cont.)

- Development of fluoride toothpastes
  - Bibby (1942): first clinical trial of fluoride toothpaste.
  - Conventional toothpaste contained dicalcium phosphate and NaF added.
  - Fluoride bound to the dicalcium phosphate causing the NaF to dissociate= inactive fluoride.
  - No caries preventive effect found.

History of Toothpastes (cont.)

- Development of fluoride toothpastes
  - Muhler er al (1954)
    - used newly developed Ca-pyrophosphate abrasive system
  - Caries preventive effect found. (10% caries reduction)

History of Toothpastes (cont.)

- Discovery of Monofluorophosphate
  - 1940s at Ozark Mahoning Company in Tulsa, Oklahoma.
  - By Dr. Harold Hodge, Dr. John Hein, Dr. Wayne White and Dr. Kanwar Shourie
  - First described the caries preventive properties of sodium monofluorophosphate.
  - Acute toxicity half that of sodium fluoride.

History of Toothpastes (cont.)

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History of Toothpastes (cont.)

- Colgate Palmolive Company marketed sodium N lauroyl sarcosinate dentifrice.
- November 1955: Proctor and Gamble marketed Crest, its stannous fluoride dentifrice.

Current Toothpastes

- Oriented towards a certain goal: i.e.
  - cleaning
  - anticaries
  - antimicrobial
  - tartar inhibition
- Contain many different substances which are necessary to obtain the desired effects i.e. abrasives, active components, motivators.

Fluoride in Toothpastes

- The first therapeutic addition to the basic dentifrice.
- Stannous fluoride (SnF_2)
- Sodium monofluorophosphate (Na MFP)
- Sodium fluoride (NaF)
- Sodium fluoride and Calcium Phosphate ($NaF/CaPO_4$)

What is the mechanism of action of fluoride? (How does it work?)

Proposed Mechanisms of Action of Fluoride

- ↑ enamel resistance to acid demin.
- ↑ rate of enamel maturation after eruption.
- Remineralization of incipient lesions
  - at the enamel surface.
  - >1ppm fluoride needed to slow demineralization process.
- Interference with microorganisms
- Improved tooth morphology.

How Does Dental Caries Begin?

- Formation of acid by microorganisms in plaque overly the enamel.
- Requires the simultaneous presence of three factors: (1) microorganisms, (2) a diet for the microorganisms, (3) a susceptible host or tooth surface.
- If (1-3) are absent = no caries.

Remember This?
Factors required for caries formation.

Remineralization

- **<u>Remineralization:</u>** deposition of calcium, phosphate, and other ions into areas of previously demineralized by caries or other causes.
- Porous or slightly demineralized enamel has a greater capacity to acquire fluoride than adjacent sound enamel (3-5x more!)
- Greater capacity of demineralized enamel to absorb fluoride. = ⬇ enamel dissolution

Physiochemical Basis

- Enamel exposed to pH of ≤ 5.5 = enamel dissolution:

$$Ca_{10}(PO_4)6(OH)_2 + 8H \rightarrow$$

$$10Ca^{++} + 6HPO^{=}_4 + 2H_2O$$

Physiochemical Basis

- Fluoride exposure reduces enamel solubility when fluorapatite is formed.

$$Ca_{10}(PO_4)_6(OH)_2 + 2F^- \rightarrow$$

$$Ca_{10}(PO_4)_6F_2 + 2OH^-$$

Demineralization and Remineralization

- Caries dissolution of enamel
  - cyclic phenomenon with phases of demineralization and reprecipitation.
  - Determined by changes in pH and ionic concentrations within the plaque and the lesion.

Differences in Types of Fluoride in Toothpastes

- SnF_2:
  - ↑ incidence of staining
  - Staining found in thick pellicle present or the porous enamel of incipient lesions.
- NaMFP and NaF:
  - widely used for dentifrices
  - slightly more effective than SnF_2 (?)
  - lack of tooth staining
  - compatible with dentifrice abrasives: Calcium fluoride formed = very insoluble

Fluoride in Toothpastes

- Source of Fluoride
  - NaF, NaMFP, and SnF_2 = major sources
  - Fluoride concentration in all major dentrifrices in USA is 0.1% (1,000 ppm):
    - equivalent to
      - **0.22% NaF**
      - **0.76% NaMFP**
      - **0.4% SnF**

Calculations of Fluoride Ingestion

- 1. Determine the % fluoride ion in a product.
- 2. Convert percentage (grams/100ml) to mg/ml.
- 3. Multiply the # of mg/ml by the amount ingested.

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Calculations of Fluoride Ingestion

- APF = Concentration listed is actual concentration of fluoride.
  - 1.23% APF = 1.23% F
- All other types of fluoride must be multiplied by their molecular weight conversion ratio:
  - NaF = 1/2, SnF = 1/4, NaMFP = 1/8
- i.e. 8% SnF ÷4 = 2% F

Calculations of Fluoride Ingestion

- (Just multiply % fluoride from step 1 by 10)
  - because you are converting grams/100ml to mg/ml.
  - i.e. 1% = 1 gram/100 ml = 10 grams/100 ml = 10,000 mg/1000 ml = 10 mg/ml
  - 2% F = 20 mg/ml
  - 1% F = 10 mg/ml

Calculations of Fluoride Ingestion

- Calculate the amount of fluoride ingested if a child swallowed all 10ml of an 8% SnF topical treatment.
  - Shortcut
- %F (from step 1) x (ml or gm) dose ingested x 10 = mg F
  - 2% F x 10 ml ingested x 10 (multiply by 10 to convert % (grams/100ml) to mg/ml = 200 mg F ingested

Fluoride Toxicity Trivia

- Safely tolerated dose (STD) = 8-16 mg/kg
- Certain Lethal Dose (CLD) = 32-64 mg/kg
- A 6 oz tube of toothpaste has 180 mg F
  - over the STD for a 10 kg (22 lb) child!!
  - Child would probably not ingest the entire tube (Yuk!!!!)

Emergency Treatment for Overdose

- **<u>≤5 mg/kg</u>**
  - oral calcium (milk) to bind the fluoride
  - observation
- **<u>5 - 15 mg/kg</u>**
  - induce vomiting
  - oral calcium
  - admit to hospital for observation
- **<u>>15 mg/kg</u>**
  - admit to hospital and induce vomiting
  - IV calcium gluconate
  - supportive measures for shock

What Toothpaste Do You Recommend for Me, Doctor?

Any Toothpaste With The ADA Seal On It!!!!

How Much Toothpaste Should I Use ?

- For children: A pea-sized amount of toothpaste to avoid fluorosis.
- For adults: Enough toothpaste to cover the whole length of the toothbrush bristles.
- **Dr. Barry Kaufman for the ADA's Dental Newsline.*

FDA Toothpaste Warning Label

- *“ If you accidentally swallow more than used for brushing, seek professional help or contact a poison control center immediately”*
- Required on all fluoride toothpastes.

FDA Toothpaste Warning Label: What does the ADA say?

- ADA Council on Scientific Affairs: unnecessarily frightening for parents and children.
- Label greatly overstates the danger posed by fluoride toothpastes.
- Child could not absorb enough fluoride from toothpaste to cause a serious problem.
- Excellent safety record argues against regulation.

The ADA's Measures to Limit Fluoride Exposure

- ADA limited the amount of fluoride allowed in the ADA-accepted toothpastes years ago.
- ADA made the toothpaste manufacturers put this statement on the toothpastes:
  - "Do not swallow. Use only a pea-sized amount for children under six. To prevent swallowing, children under six years of age should be supervised in the use of toothpaste."

The ADA Seal

- *"A symbol of Safety and Effectiveness"*
- *"For more than 60 years, a symbol of confidence to consumers and dentists"*
- 1866: ADA had statement on toothpastes.
- 1930: ADA established rigorous guidelines.

The ADA Seal

- 1931: First ADA seal of Acceptance was awarded.
- Strictly voluntary
- Manufacturers want to evaluate, test and market their products in the Seal program.
- 30% of the 1,300 dental products with the ADA seal = products sold to consumers
  - rest = products prescribed or used by dentists.

The ADA Seal: How does a product qualify?

- Manufacturer must:
  - Supply data from clinical and/or lab studies supporting the product's safety, effectiveness, and promotional claims.
  - Provide evidence that manufacturing and lab facilities are adequate and supervised.
  - Submit all advertising, promotional claims and patient education materials for review.
  - Submit ingredient lists and product info. for review.

The ADA Seal

- Manufacturer must:
  - reapply every 3 years
  - resubmit product for review and approval if the composition of the accepted product changes.

How Are The Products Evaluated?

- More than 100 consultants from the ADA's Council on Scientific Affairs and ADA staff scientists review and declare oral care products safe.
- Consultants represent a vast range of fields: microbiology, chemistry etc.
- ADA could request additional testing.
- ADA Council on Scientific Affairs awards the seal after safety and effectiveness demonstrated.

FDA Approval

- Colgate® Total™ is the first and only toothpaste to be approved by the FDA.

Common Ingredients in Toothpastes

Constituent	*Concentration (%)*
Abrasive	20 - 50
Water	20 - 40
Humectants	20 - 35
Detergent	1 - 3
Thickening agent	1 - 2
Flavoring agent	0 - 2
Sweetening agent	0 - 2
Therapeutic agent	0 - 2
Coloring or preservative	0.05 - 0.5

Common Ingredients in Toothpastes. What Do They Do?

Constituent	*Purpose*
1. Abrasive	1. Cleaning/stain removal
2. Water	2. Solvent for ingredients
3. Humectants	3. Provide creamy texture
4. Detergent	4. Surfactant/foam builder
5. Thickening agent	5. Controls viscosity
6. Flavoring agent	6. Improves taste
7. Sweetening agent	7. Enhances flavor
8. Therapeutic agent(s)	8. Active ingredient(s)
9. Color or preservative	9. Color or preservative
10. Binder	10. Holds ingred. together

Common Ingredients in Toothpastes. What Do They Do?

Constituent

- Abrasive

Examples

- Silica / hydrated silica
- Brushite
- Gibbsite
- Calcite + argonite

Purpose

- Cleaning / stain removal
- Cleaning effect of one is combined with polishing effect of another to give the best result.
- Cleaning power of abrasive depends on:
  - **type and amount of abrasive particles**
  - **surface it contacts**
  - **dilution by saliva**
  - **brushing pressure / individual**

Common Ingredients in Toothpastes. What Do They Do?

Constituent	*Purpose*
Water	Dissolves ingredients allowing them to be mixed.
	Solvent

Common Ingredients in Toothpastes. What Do They Do?

Constituent

- Humectant

Examples

- Glycerin
- Sorbital
- Polyethylene Glycol
- Paraffin oil

Purpose

- Moisturizing agent
- Protect toothpaste from drying up during storage
- Provides smooth creamy texture
- Glycerin and sorbitol are sweet = flavoring agents too.

Common Ingredients in Toothpastes. What Do They Do?

Constituent

- Detergent / Surfactant

Examples

- Na-laurylsulfate
- Sodium laurylsarcoside
- Sodium monoglyceride sulfate
- ethionates of fatty acid

Purpose

- Surface-active substances
- Decrease surface tension
- Penetrate and loosen debris
- Emulsify and remove debris along with the foaming toothpaste

Common Ingredients in Toothpastes. What Do They Do?

Constituent

- Thickening agent / binding agent

Examples

- Xanthum gum
- Carboxymethylcellulose
- Carrageenan
- Carbomer-940 A or Carbomer-956

Purpose

- Control viscosity
- Hold the toothpaste ingredients together
- Keep the creamy consistency during storage

Common Ingredients in Toothpastes. What Do They Do?

Constituent

- Flavoring agent

Examples (Crest)

- Regular flavor = wintergreen
- Mint flavor = spearmint taste
- Gel flavor = sweet spice taste.

Purpose

- Provide flavor

Common Ingredients in Toothpastes. What Do They Do?

Constituent

- Sweetening agent

Examples (Crest)

- Sodium saccharine
- Sodium cyclamate

Purpose

- Enhances the flavor

Common Ingredients in Toothpastes. What Do They Do?

Constituent

- Therapeutic agents
  - **(Active components)**

Examples (Crest)

- Fluoride
- Triclosan
- Metal ions
- Sanguinarine
- Surface-active subst.
- Chlorhexidine

Purpose

- In general:
  - **reduce caries**
  - **antimicrobial**
  - **inhibit tartar formation**
  - **desensitization**
  - **anti-inflammatory**

* ***Active substances must not be deactivated by the other ingredients.***

Common Ingredients in Toothpastes. What Do They Do?

Constituent

- Coloring / Preservative

Examples

- Titanium Dioxide
- FD&C Blue No. 1
- FD&C Yellow No. 5

Purpose

- Colorants
- Titanium Dioxide = makes toothpaste opaque. Not in gels.

ADA's Four Classifications of Toothpastes

1. Anticavity
2. Anticavity / Tartar Control
3. Anticavity / Desensitizing
4. Anticavity / Antiplaque / Antigingivitis / Tartar Control

Anticaries Toothpastes

Tartar Control Toothpastes

Common Tartar Control Ingredients

Examples

- Phosphonates
  - Tetrasodium pyrophosphate
  - Tetrapotassium pyrophosphate
  - Disodium pyrophosphate

Tartar Control using Pyrophosphates

- Stabilize the amount of calcium in saliva.
- Interferes with calculus' crystalline structure.

- Absorbed into the enamel surface as a calcium complex.
- Phosphate is freed from the crystal lattice but calcium is not.
- The calcium rich crystal lattice inhibits the growth of crystals on the enamel surface and thus ↓ the formation of tartar.

Anticavity / Desensitizing

Desensitizing Toothpastes

- Basic desensitizing ingredients:
  - strontium chloride
  - potassium nitrate
  - sodium citrate

Anticavity / Antiplaque / Antigingivitis / Tartar Control

Baking Soda Toothpastes

Baking Soda

- White crystalline powder:
  - sodium bicarbonate, bicarbonate of soda, sodium hydrogen carbonate, or sodium acid carbonate.
- Reacts with acids causing effervescence and releasing CO_2.
- Neutralizes acid
- Cleans with low abrasion
- Removes extrinsic stain
- Inhibits plaque attachment to tooth

Whitening Toothpastes

Natural Toothpastes

Natural Toothpastes

- No dyes or artificial preservatives.
- No sweeteners”Tom’s of Main.”
- Their nonfluoridated toothpaste has:
  - propolis = anitbacterial resin
  - myrrh = gingival stimulation
- Their fluoridated toothpaste has:
  - essential oils for flavor
  - finely ground calcium as abrasive

Xylitol Toothpastes

Calcium Phosphate Toothpastes

Enamelon

- Theory is by Dr. Fred Eichmiller at NIST.
- NaF and $CaPO_4$
- Provides fluoride as well as calcium and phosphate which act to strengthen the enamel.
- The soluble calcium and phosphate enhance remineralization process by converting these to naturally hydroxyapatite.